AUG 2 9 2000

K002378

510(k) Summary of Safety and Effectiveness

Trade Name:	Modular PORP & TORP
Common Name:	Partial Ossicular Replacement Prosthesis Total Ossicular Replacement Prosthesis
Classification Name:	Partial Ossicular Replacement Prosthesis (§ 874.3450) Total Ossicular Replacement Prosthesis (§ 874.3495)
Official Contact:	Alicia E. Farage Senior Regulatory Affairs Specialist Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Fax:	(901) 373-0242
Date Prepared:	August 17, 2000

The Modular PORPs and TORPs are substantially equivalent to the HAPEX TORP and PORP marketed by Smith & Nephew, Inc., ENT Division and the Tuebingen Type Bell Vario and Tuebingen Type Aerial Vario marketed by Heinz Kurz GmbH. See the chart below for summarized information in a tabular format.

Intended Use

The Modular PORP and TORP have the same intended use as the HAPEX PORP and TORP, partial/total reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect. This is also the same intended use as the Tuebingen Type Bell Vario and Tuebingen Type Aerial Vario.

Head Material

The Modular Prosthesis differs from the HAPEX PORP and TORP in the material used for the head. The head of Modular PORP and TORP is made from titanium. This material has a long history and wide use in middle ear reconstruction. However, titanium is the same material used in the Tuebingen Type Bell Vario and Tuebingen Type Aerial Vario.

Shaft Material

The Modular Prosthesis utilizes the same material as the HAPEX PORP and TORP for the shaft. The shaft is manufactured from HAPEX, a composite material that is trimmable. This composite is 40% hydroxlyapatite and 60% high-density polyethylene by volume. The However, titanium is used for the shaft in the Tuebingen Type Bell Vario and Aerial Vario.

Design Features

The shafts of the Modular Prostheses are trimmable to allow for intraoperative sizing as are the shafts of the HAPEX PORP and TORP and the Tuebingen Type Bell Vario and Aerial Vario. The heads of the Modular prostheses are flat and circular, as is the Tuebingen Type implant heads. However, the HAPEX implants have oval flattened heads.

	Modular PORP & TORP (Smith & Nephew ENT Division)	**HAPEX PORP & TORP (Smith & Nephew ENT Division)**	**Tuebingen Type Bell Vario and Aerial Vario. (Heinz Kurz GmbH)**
Intended Use	Partial/Total Reconstruction of the Ossicular Chain	Partial/Total Reconstruction of the Ossicular Chain	Partial/Total Reconstruction of the Ossicular Chain
Head Material	Titanium	Hydroxylapatite	Titanium
Head Shape	Round	Oval	Round
Shaft Material	HAPEX	HAPEX	Titanium
Intra-operative Sizing	Yes	Yes	Yes
How Supplied	Sterile	Sterile	Yes

Differences between the Titanium Prostheses and the predicate device should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2000

Smith & Nephew, Inc.
Ms. Alicia Farage
Sr. Regulatory Affairs Specialist
2925 Appling Road
Bartlett, TN 38133

Re: K002378
Trade Name: Partial and Total Ossicular Replacement Prosthesis
Regulatory Class: II
Product Code: 77ETA, 77ETB
Dated: August 02, 2000
Received: August 04, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K002398
Device Name: Modular PORP® and TORP®

Indications For Use:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis, and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

Karen H Baker

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002398